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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,736	11/14/2001	Richard Philpott	56066/45858	9454

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DBRC, IPPG of EDWARDS & ANGELL, LLP
P.O. Box 9169
Boston, MA 02209

EXAMINER
GOLDBERG, JEANINE ANNE

ART UNIT	PAPER NUMBER
1634	9

DATE MAILED: 12/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,736	PHILPOTT ET AL.	
	Examiner	Art Unit	
	Jeanine A Goldberg	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 October 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-34* is/are pending in the application.

4a) Of the above claim(s) *5, 33-34* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4 and 6-32* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 November 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☒ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *4* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. This action is in response to the papers filed October 22, 2002. Currently, claims 1-34 are pending. Claims 5, 33, 34 have been withdrawn as drawn to non-elected subject matter.

Election/Restrictions

2. Applicant's election of Group I in Paper No. 8 is acknowledged. The response argues that there is not burden to search the entire claim set because the "searches for these groups would overlap significantly." This argument has been thoroughly been reviewed, but found not persuasive because separate classifications is a prima facie case of burden. The products of Groups II, III, IV are separately classified. Furthermore, the searches for Group II, III, IV and the elected Group I are not coextensive.

The requirement is still deemed proper and is therefore made FINAL.

This application contains claims 5, 33, 34 drawn to an invention nonelected with traverse in Paper No. 8. A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Priority

3. This application claims priority to provisional application 60/248,876, filed November 15, 2000.

Oath/Declaration

4. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing or post office address of each inventor. A mailing or post office address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing or post office address should include the ZIP Code designation. The mailing or post office address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not identify the citizenship of each inventor.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either on an application data sheet or supplemental oath or declaration.

Specifically, there is no information in the oath regarding the first named inventor, Richard Philpott. Appropriate correction is required.

Claim Rejections - 35 USC § 112- Second Paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-4, 6-10, 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

A) Claims 1-4, 6-7 are indefinite over the recitation "including preserving means sorbed to the solid matrix..." because it is unclear whether the preserving step is an active process step which is required or whether the preserving is inherent in the method step of the applying to a matrix. It is unclear how the step relates to the method as a whole. Similarly, "to derive genetic material from the sample" is unclear whether by merely preserving the genetic material "derives" the genetic material from the sample. As written it is unclear what is required by the method. Thus, the metes and bounds of the claimed invention are unclear.

B) Claim 2 is indefinite over the recitation "cells" because Claim 1 does not provide any "cells." Thus, cells, in Claim 2, lacks proper antecedent basis.

C) Claim 4 is indefinite over the recitation "dissociating the cells of the tissue sample" because it is unclear whether the "cells of the tissue sample" are dissociated from the tissue itself or from another source. Thus, it is unclear from what the cells are dissociated. Clarification is requested.

D) Claims 8-10 require a method of isolating and analyzing genetic material, however, it is unclear whether the method steps achieve the preamble because the final process step is only directed to analyzing the genetic material. With respect to the isolating step, it is unclear whether the isolating step was accomplished by the lysing of the cells/virons or whether the claim is intended to mean isolating the genetic material

from the solid medium also. Clarification is requested. Further, Claim 9 is indefinite over the recitation "dissociating the cells of the tissue sample" because it is unclear whether the "cells of the tissue sample" are dissociated from the tissue itself or from another source. Thus, it is unclear from what the cells are dissociated. Clarification is requested.

E) Claim 16-18 are indefinite over the recitation "dissociating the cells of the tissue sample" because it is unclear whether the "cells of the tissue sample" are dissociated from the tissue itself or from another source. Thus, it is unclear from what the cells are dissociated. Clarification is requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

6. Claims 1-4, 6, 8, 10 are rejected under 35 U.S.C. 102(e) as being anticipated by Smith et al (US 2001/0000149 A1, Publication Date: April 2001).

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Smith et al (herein referred to as Smith) teaches a solid medium and process for the storage and rapid purification of nucleic acid. Smith teaches a method of storing the genetic material and subsequently analyzing the genetic material which includes the steps of immobilizing the genetic material on a support while enabling cellular lysis and release of genetic material from the lysed cells and stabilizing the immobilized released genetic material on the support (abstract)(limitations of Claim 1a, 1b, 6, 8). The genetic material may then be eluted to generate a soluble genetic material fraction and analyzed (abstract)(limitations of Claim 1c). Smith teaches that the chemical coating solution is reacted with the filter membrane to produce the filter membrane of the invention. The chemical coating solution comprises a weak base, a chelating agent and an anionic surfactant or detergent (para 52)(limitations of Claim 3). The nucleic acid of the invention may be any form of nucleic acid containing material such as blood, cultured mammalian cells, saliva, urine, cultured bacterial cells, yeast, solid tissue, for example (para 55)(limitations of Claim 4, 10). The nucleic acid may be eluted from the storage medium by elution for subsequent downstream analysis such as PCR, LCR, reverse transcription or sequencing (para 56). Smith teaches that the invention may be

used in genomic, for example, forensic application, paternity/maternity identification (para 63-64)(limitations of Claim 2). As provided in Example 4, genomic DNA may be prepared from saliva (page 7-8). The

7. Claims 1-3, 6, 8, 10 are rejected under 35 U.S.C. 102(b) as being anticipated by Burgoyne (US Pat. 5,807,527, September 1998).

Burgoyne teaches a method of storage of DNA using solid medium having a compound which protects against degradation of DNA incorporated into or absorbed on the matrix, and for recovery of DNA or in situ use of DNA (abstract). Blood dried onto filter paper is a proven alternative and has been shown that DNA can be extracted and isolated from dried blood spots in a form and in sufficient quantities for use in DNA analysis (col. 1, lines 60-65). Burgoyne teaches that the solid matrix may comprise a solid support such as an absorbent cellulose-based paper or a micromesh of synthetic plastics material. Moreover, Burgoyne teaches that the solid medium comprises a composition comprising a weak base, a chelating agent and an anionic surfactant or detergent (col. 2, lines 60-64)(limitations of Claim 3). DNA on filter paper specially treated in accordance with this invention was purified in situ, then subjected to the polymerase chain reaction (col. 4, lines 37-30). Burgoyne teaches that treated paper was much more efficient than untreated paper. Treated paper gave recoveries of approximately 100% where as untreated paper only has about 10% recovery (col. 6, lines 8-10). Burgoyne teaches that exon 2 of the nRAs protoconcogene and male specific Y chromosome repeat, were genotyped (limitation of Claim 2).

8. Claims 1-4, 6, 8-10, 19-24, 26-29, 31-32 are rejected under 35 U.S.C. 102(a) as being anticipated by Higgins et al. (Am. J. Trop. Med. Hyg. Vol. 62, Vol. 2, pages 310-318, February 2000) in view of Gibco BRL Products Catalog (FTA Card, page 2-7, 1999) and further in view of Burgoyne (US Pat. 5,496,562, March 1996).

Higgins teaches detection of Francisella tularensis in infected mammals and vectors using a probe-based polymerase chain reaction. Higgins uses specially formulated filter paper (FTA) for rapid sample preparation. Higgins teaches taking clinical samples from swabs from skin ulcers of patients suspected of being infected with tularemia (page 312, col. 1). The DNA was spotted as 3-5 ul aliquots onto FTA filter paper. Upon receipt at USAM-RIID, the samples were processed. Higgins teaches evaluating the FTA paper by performing a PCR reaction with primers specific for the F. tularensis tul 4 gene (page 312, col. 2). The stability of templates and the ease of intercontinental transport by using DNA deposited onto FTA filter papers was demonstrated. Higgins teaches that FTA paper analysis is a simple, inexpensive, and rapidly performed sample preparation method. Therefore, Higgins teaches a method of isolating cells on a swab and contacting the isolated cells from the swab onto a FTA filter paper and analyzing the nucleic acid.

As provided by Gibco BRL Products catalog, FTA paper is impregnated with a proprietary formulation. Moreover, Gibco teaches that the product is subject to Patent 5,496,562. The formulation of Patent 5,496,562 absorbed on the paper is a weak base,

a chelating agent and an anionic surfactant or detergent. Thus, Higgins teaches every limitation of the claimed invention.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-4, 6-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martinson et al (US Pat. 5,811,061, September 22, 1998) in view of Burgoyne (US Pat. 5,807,527, September 1998).

Martinson et al. (herein referred to as Martinson) teaches a method for creating a leukocyte rich sample. Martinson teaches leukocytes are a source of infectivity in

blood and they provide desirable material for diagnostic assays. The leukocyte are separated via filters. The filter may be treated to lyse the cells contained in the filter (col. 6, lines 20-24). The cell lysate may then be flushed out of the filter sing an isotonic saline solution and collected. The resultant cell lysate may be then used as a test material for diagnostic assays (col. 6, lines 30-35).

Martinson does not specifically teach collecting the cell lysate on a FTA filter paper. However, FTA filter paper is suitable for storage of blood samples as well as a variety of cells and tissues for PCR analysis and other genomic applications.

However, Burgoyne teaches a method of storage of DNA using solid medium having a compound which protects against degradation of DNA incorporated into or absorbed on the matrix, and for recovery of DNA or in situ use of DNA (abstract). Blood dried onto filter paper is a proven alternative and has been shown that DNA can be extracted and isolated from dried blood spots in a form and in sufficient quantities for use in DNA analysis (col. 1, lines 60-65). Burgoyne teaches that the solid matrix may comprise a solid support such as an absorbent cellulose-based paper or a micromesh of synthetic plastics material. Moreover, Burgoyne teaches that the solid medium comprises a composition comprising a weak base, a chelating agent and an anionic surfactant or detergent (col. 2, lines 60-64)(limitations of Claim 3). DNA on filter paper specially treated in accordance with this invention was purified in situ, then subjected to the polymerase chain reaction (col. 4, lines 37-30). Burgoyne teaches that treated paper was much more efficient than untreated paper. Treated paper gave recoveries of approximately 100% where as untreated paper only has about 10% recovery (col. 6,

lines 8-10). Burgoyne teaches that exon 2 of the nRAs protoconcogene and male specific Y chromosome repeat, were genotyped (limitation of Claim 2). Burgoyne teaches that DNA may be stored on the solid matrix having a composition thereon are suited for performance under automated conditions. Burgoyne teaches that the means of storage may be established for long term storage and may be kept in orderly, low-volume files (col. 4-5).

There, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to have modified the method of Martinson to further include the collection of the cell lysate onto the solid medium taught by Burgoyne. Martinson teaches that leukocytes are desirable for diagnostic assays. Moreover, Burgoyne teaches that DNA may be stored on the solid matrix having a composition thereon are suited for performance under automated conditions. Moreover, Burgoyne teaches the benefits of using the solid support for storage of DNA for long periods of time. The benefits of the storage of the DNA upon the solid matrix additional includes the low-volume files as compared to liquid blood samples which require more care. Therefore, the ordinary artisan would have been motivated to have purified leukocytes from blood for the expected benefit of diagnostic importance, taught by Martinson, and stored the sample DNA upon a solid matrix of Burgoyne for the expected benefits of long-term, low-volume storage, automation and ease in handling specimens.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the

unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

11. Claims 1-4, 6, 8, 10 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 16 of copending Application No. 09/507,548.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented. It is noted that the 09/507,548 application has been allowed, however, the patent has not been published.

An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim is not patentably distinct from the reference claim(s) because the examined claim is either anticipated by or would have been obvious over, the reference claim(s). See e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

Although the conflicting claims are not identical, they are not patentable distinct from each other because Claim 1 of the instant application is generic to all that is recited in Claim 16 of U.S. Application No. 09/507,548. That is, Claim 16 of 09/507,548 falls

entirely within the scope of Claim 1, or in other words, Claim 1 is anticipated by Claim 16 of 09/507,548. Here, claim 16 of U.S. Application No. 09/507,548 recites a method of storing a genetic material and subsequently analyzing the genetic material by containing cells having genetic material with a glass microfiber matrix sorbed with an FTA purification reagent while enabling cellular lysis and release of genetic material from the lysed cells, immobilizing and stabilizing the released genetic material, and disposing the matrix having the genetic material immobilized therein into heated water in the temperature range of 65C to 100C and releasing the genetic material into the heated water to generate a soluble genetic material fraction, and analyzing the eluted genetic material.

Moreover, the method of Claim 16 differs from Claim 1 herein in that it fails to disclose the elements of the matrix, an analyzing step for phenotyping, and dissociation of cells from tissue. However, portions of U.S. Application No. 09/507,548 support each of these elements. Therefore, it would have been obvious to modify the method of Claim 16 of U.S. Application No. 09/507,548 such that the matrix comprised a base, chelating agent and an anionic surfactant; the genetic material is analyzed for phenoytping and the cells are dissociated from tissue. One having ordinary skill in the art would have been motivated to make such a modifications as per the teachings the supporting portions of U.S. Application No. 09/507,548.

Conclusion

12. No claims allowable over the art.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jeanine Goldberg whose telephone number is (703) 306-5817. The examiner can normally be reached Monday-Friday from 8:00 a.m. to 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax number for this Group is (703) 305- 3014.

Any inquiry of a general nature should be directed to the Group receptionist whose telephone number is (703) 308-0196.

J. Goldberg

Jeanine Goldberg
December 23, 2002

W. Gary Jones
Supervisory Patent Examiner
Technology Center 1600